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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,003	04/21/2000	HARRY ZSCHEEG	A0008/7000	8603

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EXAMINER
WOO, JULIAN W

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,003	ZSCHEEG, HARRY	
	Examiner	Art Unit	
	Julian W. Woo	3731	

-- Th MAILING DATE of this communication app ars on th cov r she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13,19-22 and 27-45* is/are pending in the application.

4a) Of the above claim(s) *12,13,19-22 and 31-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informality: On pages 3, 6, and 7, references to the claims, in the "Summary of the Invention," should be deleted, since the invention should be independently described before claims are made. Appropriate correction is required.

Drawings

2. Figures 1 and 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Election/Restrictions

3. Claims 12, 13, 19-22, and 31-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 27, line 12, "the stent delivery device" lacks antecedent basis. With respect to claim 30, line 1, "A process" lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 8-10, and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau et al. (5,514,154). With respect to claims 1, 3, and 27, Lau et al. disclose in figures 1-5, an expandable stent (10) with an elastic tubular lattice structure having first and second end zones, a longitudinal direction, a radial direction, wall segments with intersections (at 13), and wall segments with interrupted intersections (at portions of 12), where expansion of the wall segments is formed by an arcuate curvature. With respect to claims 8-10, col. 6, lines 61-63 disclose that the stent consists of a metallic, shape memory alloy or a nickel-titanium alloy. With respect to

claims 28 and 29, col. 4, lines 30-64 disclose a delivery system with a balloon dilation catheter applied with the Seldinger technique.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4, 5, 11, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. Lau et al. disclose the stent and stent delivery system substantially as claimed, but do not disclose stent wall intersections interrupted at substantially two thirds of all intersections, aperture widths of maximally 9 mm when the stent is expanded, and alloy moieties as claimed. However, Lau et al. discloses in col. 3, lines 5-15, that the number of elements (13) interconnecting adjacent cylindrical elements (12) can be varied, and by inference, the number of interrupted intersections can be varied. Also, Lau et al. disclose, in col. 5, lines 23-28, that cylindrical elements

can be closely spaced at regular intervals, but do not disclose aperture widths. Lau et al. disclose, in col. 2, lines 42-56 and in col. 7, lines 12-24, nickel-titanium alloys for use in a stent, but do not disclose the moieties. Nevertheless, it would have been a matter of design choice to one of ordinary skill in the art at the time the invention was made, to configure the stent as claimed and manufacture a stent with alloy moieties as claimed. Stent wall intersections interrupted at substantially two thirds of all intersections can be chosen depending upon the desired longitudinal flexibility of the stent. An aperture width can be chosen according to the support required for a vessel wall or its flaps or dissections. The moiety of a nickel-titanium alloy can be chosen to achieve a desired elasticity for the reversible transformation of a stent from the deformed or compressed state to the expanded state.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. in view of Fogarty et al. (EP 792627). Lau et al. disclose the stent substantially as claimed, but do not disclose a wall thickness between 0.2 mm and 0.3 mm. Fogarty et al. teach, in col. 10, lines 14-18, a stent with a wall thickness between about 0.1 mm and 0.5 mm. It would have been obvious to one having ordinary skill in the art, at the time the invention was made, in view of Fogarty et al., to modify the stent of Lau et al., so that it has a wall thickness within the range as claimed. Such a stent would have the mechanical strength for reinforcing an aortic aneurysm.

Response to Amendment

11. Applicant's arguments filed on October 7, 2002 have been fully considered but they are not persuasive.

Regarding the arguments with respect to rejections under 35 U.S.C. 112: See the rejection above.

Regarding the arguments with respect to rejections under 35 U.S.C. 102: Lau et al. do disclose "wall segments [that] are expanded in the radial direction," where radial expansion of the stent (by a balloon) causes another radial expansion, i.e. the "outward tipping" of the interrupted intersections of the cylindrical members of Lau et al., which can be independently expanded to implant the stent in a variety of body lumen shapes or curvatures. Upon implantation of the stent, Lau et al., in col. 5, lines10-24, disclose that, as the claim states, "a reduction of the inner [stent] lumen due to wall segments at the interrupted intersections is prevented." That is, blood flow interference is prevented, because wall segments do not impinge the artery lumen as well as the stent lumen.

Regarding the arguments with respect to rejections under 35 U.S.C. 103 on Lau et al.: See the rejection above. Regarding the arguments with respect to the Fogarty reference: Fogarty provides a teaching reference of modifying the stent of Lau et al., since Fogarty discloses an expandable stent with wall segments having intersections and interrupted intersections.

Regarding the arguments with respect to the restriction requirement: The restriction requirement is proper, because the making of a stent by a process of molding, welding, or chemical etching is not, as the Applicant stated, "beside the point." That is, the claimed process includes providing and slotting a tubular element in order to produce a stent. However, a stent can be produced, for example, by molding a material into a tubular element with slots or by welding wires into a tubular element with slots. In

short, the expandable stent as claimed can be produced by a process different from the process of claim 12.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schnepp-Pesch et al. (5,707,386) teach a stent with wall segments having intersections and interrupted intersections.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.

Julian W. Woo
Patent Examiner

December 11, 2002